

Policies Repository



Policy Title Paliperidone (Invega®)/Quetiapine fumarate (Seroquel XR®)

Policy Number FS.CLIN.41

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Paliperidone (Invega®)** is indicated for the treatment of schizophrenia.

Quetiapine fumarate (Seroquel XR®) is indicated for the treatment of schizophrenia.

The use of paliperidone (Invega®) and quetiapine fumarate (Seroquel XR®) require prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Paliperidone (Invega®) is a benzisoxazole antipsychotic. Paliperidone is the major active metabolite of risperidone. While the mechanism of action is unknown, its proposed therapeutic activity is antagonism of both the central dopamine Type 2 (D[2]) and serotonin Type 2 (5HT [2A]) receptors. It also has antagonistic effects on the alpha-1 adrenergic, alpha-2 adrenergic, and H1 histaminergic receptors. The overall results of these actions produce control of schizophrenic symptoms and reduction in recurrent symptoms. There have been no clinical studies to demonstrate that paliperidone (Invega®) is more effective than current formulary agents in the treatment of schizophrenia. In addition, the safety and efficacy of paliperidone (Invega®) has not been evaluated past six weeks.

Quetiapine fumarate (Seroquel XR®) is an atypical antipsychotic with an unknown mechanism of action. Quetiapine fumarate (Seroquel XR®) is thought to exert its effect via dopamine type 2 (D2) and serotonin type 2 (5HT2) antagonism. Quetiapine fumarate (Seroquel XR®) is an extended-release product and should be administered once daily. Quetiapine fumarate (Seroquel XR®) is a new formulation of a preferred agent.

Policy Guideline Inclusion

Paliperidone (Invega®) is approved when there is a documentation of a diagnosis of schizophrenia and **one** of the following:

- Documentation of a trial and failure of, or contraindication to, at least one of the following medications:
 - Aripiprazole (Abilify®)
 - Risperidone (Risperdal®)
 - Quetiapine fumarate (Seroquel®)
 - An olanzapine-containing product
- Documentation of stabilization from an institutional setting
- Documentation of current stabilization

Quetiapine fumarate (Seroquel XR®) is approved when there is a documentation of a diagnosis of schizophrenia or bipolar disorder and **one** of the following:

- Documentation of a trial and failure of, or contraindication to, at least one of the following medications:
 - Aripiprazole (Abilify®)
 - Risperidone (Risperdal®)
 - Quetiapine fumarate immediate-release (Seroquel®)
 - An olanzapine-containing product
- Documentation of stabilization from an institutional setting
- Documentation of current stabilization

Policy Guideline Exclusion

Paliperidone (Invega®) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of schizophrenia
- No documentation of a trial and failure of, or contraindication to, at least one of the following medications:
 - Aripiprazole (Abilify®)
 - Risperidone (Risperdal®)
 - Quetiapine fumarate (Seroquel®)
 - An olanzapine-containing product
- No documentation of stabilization from an institutional setting
- No documentation of current stabilization

Quetiapine fumarate (Seroquel XR®) is denied when **any** of the following exclusion criteria are present:

- No documentation of a diagnosis of schizophrenia or bipolar disorder
- No documentation of a trial and failure of, or contraindication to, at least one of the following medications:
 - Aripiprazole (Abilify®)

- Risperidone (Risperdal®)
- Quetiapine fumarate immediate-release (Seroquel®)
- An olanzapine-containing product
- No documentation of stabilization from an institutional setting
- No documentation of current stabilization

Policy List of Applicable Drugs

Brand Name	Generic Name
Invega	Paliperidone
Seroquel XR	Quetiapine fumarate

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

Invega® (paliperidone). [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed May 7, 2008.

Invega® (paliperidone) [prescribing information]. Titusville, NJ: Janssen, LP; 2008.

Facts & Comparisons. Seroquel XR®. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com>. Accessed May 7, 2008.

Kahn RS, Schulz SC, Palazov VD, et al. Efficacy and tolerability of once-daily extended release quetiapine fumarate in acute schizophrenia: a randomized, double-blind, placebo-controlled study. *J Clin Psychiatry*. 2007;68(6):832-842.

Seroquel XR®. [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed May 7, 2008.

Seroquel XR® [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; 2008.

Policy Link to Related Policies

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01/06/2009 14:39:48

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